Testimony to the Task Force on Drug Importation
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Patricia M. Danzon PhD.

Good afternoon, Mr. Chairman. I appreciate the opportunity to address the Task Force today. My name is Patricia Danzon. I am the Celia Moh Professor of Health Care Systems, Insurance and Risk Management at the Wharton School of Management at the University of Pennsylvania. I have a Ph.D. in Economics from the University of Chicago. Since 1985 I have done research and taught courses in Health Economics, Pharmaceutical Economics and Management, and Comparative Health Care Systems at the Wharton School, at the undergraduate, MBA, PhD and Executive levels.

Because my expertise and research are mainly on the economics of drug pricing, international price comparisons and incentives for R&D, my comments today will focus mainly on the potential short- and long-term impact on drug prices associated with importing drugs from Canada and other countries, and the effects on drug research and development (R&D). Effects of importation on safety, administrative resource costs, patent rights and other issues are equally importation but are not central to my area of expertise.

Let me start by stating my conclusion: the precise impact of importation on drug prices to US consumers is uncertain, depending on a number of factors. What is certain is that the savings to US consumers will be less than might be expected from looking at the current differences in prices charged by US pharmacies vs. foreign pharmacies for specific drugs. But perhaps paradoxically, even if importation does little to lower prices to US consumers, it could have a significant adverse effect on incentives for R&D and on the development of new drugs.

In analyzing effects of importation on drug prices, it is important to distinguish prices at 3 levels of the drug distribution chain: manufacturer prices are the prices at which manufacturers sell to wholesalers; wholesaler prices are the prices at which wholesalers sell to pharmacies or hospitals; and retail or consumer prices are the prices at which pharmacies sell to consumers or third party payers. The objective of importation proposals is to reduce retail prices paid by consumers and third party payers.

If importation is adopted as US policy, the savings to consumers and payers as a percent of their total drug spending will be less than typical differentials between current retail prices in the US and say Canada for specific products, for several reasons. First, the products and formulations used in the US are often different from the products and formulations sold in foreign markets, which limits the scope for importation. Second, the adoption of importation as national policy is likely to trigger limited supply to potential export countries in the short run. Third, in the longer run increases in foreign prices and non-launch in relatively low-price countries will further limit the potential for importation. Fourth, even if US wholesalers and pharmacies were able to obtain a

significant supply of imported drugs at lower prices, the supply may be insufficient to assure competition which is necessary to achieve the pass-through of savings to consumers and payers. Thus the main beneficiaries would be the importers and pharmacies. Importation is likely to reduce access for foreign consumers, with little savings for US consumers and fewer new drugs available for consumers globally. Let me address each of these points in turn:

Heterogeneity of products Although some drugs are truly global products, there is considerable heterogeneity across countries in the compounds available, presentation forms and strengths. This product heterogeneity, which reflects differences in medical norms, preferences, reimbursement etc., will significantly limit the range of products subject to importation. This assumes that pharmacies/payers can only substitute imported products when they are identical in dosage form, strength and manufacturer to the US product.

Some evidence on the heterogeneity of markets is available from our comparison of prices, availability and utilization in the US and eight comparison countries (Danzon and Furukawa, 2003). We started with a sample of the 249 leading molecules in the US in 1999 (by unit volume), that accounted for over 60 percent of sales in the US. These same compounds also accounted for over 60 percent of sales in Canada and the UK, but only 30-40 percent of sales in Japan and the European countries. However, the drugs that were identical in formulation and strength in both the US and the comparison countries accounted for only about 30 percent of sales in the US, Canada and the UK, and 15 percent of sales in the other countries. The fraction with same manufacturer would be even lower. Thus although the pharmaceutical market in Canada and the UK are similar to the US, markets in other European countries and Japan are significantly different, in that many compounds that are available in the US are not available in these markets; even for matching compounds the formulations and strengths are often different; and these matching formulations account for a smaller percent of sales in these countries than in the US. Both non-matching formulations and small sales of matching formulations will limit the potential supply of imported drugs.

In fact, if importation becomes national policy in the US, manufacturers may rationally respond by increasing the variation in formulations and strengths between the US and potential export countries. With different strengths and formulations, US patients would face at minimum inconvenience and possibly also confusion and risks to health from using imported products: for example, they might have to cut foreign pills in half to achieve the US dosage, or take a foreign pill three times a day rather than a once-a-day US formulation. Inconvenience, risks and uncertainty arising from imperfect matching of foreign and US formulations would likely reduce the demand for imports.

Supply restrictions For drugs for which importation is feasible, because the same formulations are sold in the US and abroad, manufacturers are likely to limit their sales to exporting countries to the quantities required for those countries, in order to reduce the excess supply available to export to the US. Such restrictions are a rational, unilateral response of manufacturers and do not require or presuppose collusion between

manufacturers or between manufacturers and foreign wholesalers. Some manufacturers have reportedly already started limiting supply of certain products to Canada. Supply restriction is the main, feasible response in the short run for drugs that have already been launched.[1]

Assuming that such supply restrictions are upheld as legal – and there is no economic reason why they should not be, since they reflect unilateral, strategic decisions – their effectiveness at limiting the supply of exports to the US will depend on the number of countries approved as potential exporters and willingness of wholesalers to divert product to the US before satisfying their domestic consumers. To illustrate, assume that manufacturers could limit the supply to each country to that country's needs, but that wholesalers/pharmacists ship 20 percent to the US, leaving 20 percent of their domestic consumers unsatisfied. If Canadian volume were 10 percent of US volume, this 20 percent of Canadian volume would satisfy only 2 percent of the US market. If all European markets were included as potential export countries, if we assume that aggregate EU volume is roughly equivalent to aggregate US volume, then 20 percent of sales from Canada plus the EU would satisfy 22 percent of US demand. [This ignores the differences in product mix discussed earlier.]

Thus because the US market volume is large relative to the potential exporting markets, a large share of the exporting countries' volume would have to be shipped to the US in order to satisfy a significant fraction of US demand. For example, even if the entire volume of shipments sent to Canada were exported back to the US, this volume would be insufficient to affect prices to consumers in the US. I return to this below. The US accounts for roughly 50 percent of global pharmaceutical sales, Europe accounts for roughly one third of sales. But even if Europe and Canada together had total unit volume equal to unit volume in the US, these aggregate data would greatly overstate the potential for importing products used in the US from these markets because of differences in the compounds, presentations, and formulations in these different markets described earlier.

Adjustments in prices and availability abroad In the longer run and, in particular, for new products that have yet to be launched, the likely manufacturer response to a broad importation policy in the US is to attempt to reduce the US-foreign price differentials. In countries that regulate drug prices, a manufacturer's ability to influence price is greatest at launch; thereafter, price increases usually require approval and are rare. If the US adopts a broad importation policy, economy theory suggests that manufacturers would rationally attempt to set a uniform price in the US and all potential export countries. This single price would be a weighted average of the prices that would have been charged in each market separately, where the weights are each country's share of

[1] For launched products, other possible responses are less practical: changing formulations could require costly new trials to obtain regulatory approval and switching physicians and patients to the new formulations; raising foreign prices is usually not feasible in regulated markets, and manufacturers are usually reluctant to withdraw existing products.

sales. Because the US is the largest market, this optimal single price is likely to be close to the current US price.[2]

If manufacturers do move to a uniform pricing strategy, seeking foreign prices that are close to current US levels, the price differentials may be insufficient to warrant the costs of importation and incentives for importation will be reduced. This effect, that permitting importation creates incentives for manufacturers to try to raise prices in foreign markets close to US price levels, is the intent of some proponents of importation. If this were to occur, the hope is that US consumers might benefit if manufacturer revenues and hence volume of R&D and new drugs increased.

But if manufacturers could profitably charge higher prices abroad, they would presumably already have done so. The reason they have charged lower prices is that foreign countries are not willing to pay higher prices or, if they do, do so only with very tight restrictions on use, such that manufacturers' overall revenues would be lower at the higher prices. Thus the likely response to attempts by manufacturers to raise prices abroad is that some countries, especially those with relatively low income, will be unwilling or unable to pay the higher prices, in which case the drugs will not be launched or will be launched only after delay of months or years. In the less extreme case, the drugs may be launched at the higher price, but utilization will be severely restricted.

Thus in the longer run, the potential for importation will be reduced by reduced price differentials on newly launched products. However, this is likely to reflect primarily an increase in prices abroad, not a reduction in prices in the US. But because some foreign countries, particularly those with relatively low income or tight controls on health care expenditures, will be unable or unwilling to pay higher prices for drugs, fewer drugs will be launched in these countries. Our recent study of launch delays and non-launch of new drugs in the 1990s provides evidence on this issue (Danzon, Wang and Wang, 2003). We studied the launch in 25 countries over 80 new chemical entities (NCEs) that were first launched in the 1990s. We found that countries with relatively low prices had fewer drugs launched and longer launch delays, and that additional launch lags were found in the EU countries that are major parallel exporters. This evidence is consistent with the hypothesis that manufacturers rationally choose to delay launch or not launch at all in markets where a relatively low price might erode potentially higher prices in other markets. Thus the prediction is that adoption of importation in the US will lead to higher prices for new products in countries that are potential exporters, with non-launch or delayed launch or restricted utilization. In either case, foreign consumers lose due to reduced access and higher prices and US consumers do not gain, because US prices are not significantly lower, manufacturer revenues are lower and there is less R&D and fewer new drugs than before importation was adopted.

This prediction, that in the long run importation by the US makes foreign consumers worse off with minimal or no gains for US consumers, is supported by economic analysis. Economic theory has examined the question of optimal (welfare maximizing) pricing in

[2] For a formal statement of optimal pricing with and without market segmentation, see Danzon (1997), Danzon and Towse (2003).

the context of a global industry, such as pharmaceuticals, which makes investments in R&D that can benefit consumers globally but where demand elasticity (price sensitivity) differs significantly across markets, due to income and other factors. In such a context, social welfare is higher if prices differ across countries/markets, depending on demand conditions in each market, compared to a uniform price level in all markets. The reason is that with uniform prices, utilization falls significantly in the more price-sensitive markets, leading to lower consumer welfare, lower manufacturer revenue, and fewer new drugs. Such outcomes are also inequitable, assuming that it the lower-income markets that are more price sensitive, so suffer the greatest reductions in access when prices are increased to a uniform level. For more detailed analysis, see Danzon, 1997; Dumoulin, 2001; Danzon and Towse, 2003; Hausman andf Mackie-Mason, 1988.

Effects on prices to consumers Even if wholesalers were able to locate and import lower priced drugs from abroad, there is no guarantee that any savings would be passed on to third party payers and consumers. Parallel trade within the European Union has been legal for years. The consensus of most studies is that much of any savings is captured by either the wholesalers or pharmacies. However, we should not generalize immediately from this EU experience to the US. The extent of pass through to consumers of any savings from importation depends critically on competition and reimbursement of retail pharmacy.

In the US, most pharmacy benefit managers, Medicaid and other third party payers reimburse pharmacies for the drugs that they dispense based on a discounted list price -- for example, average wholesale price (AWP) minus 15-18 percent -- plus a dispensing fee. The discount percentage reflects the average discount or differential between the AWP list price and the price at which pharmacies actually acquire drugs from wholesalers, compared to the AWP list price. If wholesalers were able to import some of their drugs from abroad at prices below the average actual wholesale price in the US, their incentive to pass this savings on to pharmacies would depend on the extent of competition between importers. If, as is likely to be the case, there is limited supply from abroad, the market dynamics would be many pharmacies competing for the supply from a few importers. In that environment, the importers would face little competitive pressure and would be able to retain much of the margin themselves.

Thus a necessary condition for savings to be passed on by importers to pharmacies is that there must be a sufficient number of importers and a sufficient supply of product to create competitive supply conditions. This seems unlikely for most products, for reasons outlined above related to the size of the US market compared to other countries, mismatch of products and limits on supply to potential exporting countries.

Even if for some high volume drugs, competition among importers were sufficient to force them to pass on the savings from lower foreign prices to retail pharmacies, the next question is whether pharmacies would pass on their savings to payers and consumers. Since most payers reimburse pharmacies at fixed percentage of a list price, these payers might increase the percent discount, to capture the expected or average savings realized by pharmacies. This approach has been adopted by government payers in the UK and the

Netherlands. The so-called "clawback" or reduction in payment to pharmacies is intended to reflect the average savings realized by pharmacies from purchasing parallel traded products. Using an average clawback or discount percent is likely to be adopted by US payers, since it preserves incentives for pharmacies to seek out cheaper products and is administratively practical. The alternative, of auditing actual acquisition costs for all pharmacies and adjusting their payment levels based on their actual acquisition costs is administratively burdensome and, more important, would eliminate incentives for pharmacies to seek out cheaper drugs from wholesalers. However, if payers in the US attempt to capture the savings from importation by reducing their average payment level to pharmacies, to reflect the average expected savings, this would penalize those pharmacies who chose to dispense only US-sourced drugs, in the interests of their patients' safety, and/or those pharmacies who lacked the competitive clout to obtain the limited supply of imported drugs. Thus resistance to such reductions in pharmacy reimbursement would be likely.

Finally, even if third party payers were able to extract the average savings from importation from pharmacies, there is no guarantee that prices would be reduced for patients who pay for drugs out-of-pocket. Again, the incentive for pharmacies to reduce prices to consumers depends on the extent of competition. If the supply of imported drugs is limited and sporadic, competitive pressures to pass through the limited and sporadic savings would be weak and hence savings to patients would be limited at best.

Broader Policy Considerations Related to Importation

Average prices differences

Our analysis of differences in manufacturer-level prices between the US and eight comparison countries (Canada, France, Germany, Italy, Japan, the UK, Mexico and Chile) using 1999 prices (Danzon and Furukawa, 2003) found that price differentials roughly reflected income differentials. The major exceptions are Mexico and Chile, whose prices are similar to Europe or Canada while per capita income is much lower. These high prices, relative to income, result in much lower per capita drug consumption in these two countries than in the other countries in the study. This illustrates the potential effect on access to drugs in poorer countries if importation becomes legal in the US and leads to higher prices in other countries.

Factors Contributing to Price Differences

International price differences for drugs reflect many factors, of which income and regulatory systems are particularly important. Most countries regulate manufacturer prices for drugs, either directly (France, Italy, Spain) or indirectly through controls on reimbursement (Germany, Japan), overall drug spending limits (France, Italy) or rate of return on capital (the U.K.). The Canadian federal government controls launch prices for newly launched originator products and limits post-launch price increases; provincial governments have significant monopsony (large buyer) power in operating their formularies which may further reduce prices. In addition, current price differentials reflect movements in exchange rates. Most regulatory systems do not allow post-launch

price increases. Thus even if a product is launched at the same price in the US and some foreign country, movements in exchange rates lead to price divergence over time.

Note that cross-national price differences for physician and hospital services are often at least as large as price differences for drugs (Danzon and Furukawa, 2003). Again, these medical price differences reflect differences in income levels; the structure, culture and norms of foreign health care systems; and insurance and regulatory systems.

Overall Efficiency of Importation of Drugs

Leaving aside issues of counterfeits and safety, the main economic concern is that importation would result in at most very modest savings to US payers and consumers, because supply would be limited, due to product heterogeneity, supply restrictions and the intrinsically large size of the US market relative to other countries; moreover, intermediaries would capture much of any savings that might be available. In the longer run, higher prices and reduced access to new drugs in foreign countries would reduce their access to medicines, with adverse effects on their health. Lower global revenues of pharmaceutical companies will reduce incentives for R&D and reduce the flow of new products for everyone. Moreover, permitting importation by third parties of on-patent products would significantly undermine traditional patent protection for pharmaceuticals compared to other industries. If this weakening of intellectual property protection were to spread to other countries, this could further lower prices abroad. Currently, the European Union (EU) permits parallel trade only within the EU, but does not permit importation of on-patent drugs from non-EU countries.

Trade normally increases consumer welfare, by shifting supply to the country that is the most efficient supplier, thereby permitting consumers in other countries to benefit from lower prices. However, such efficiency gains are small if any, in the case of importation of on-patent pharmaceuticals, because the lower prices in the exporting country primarily reflect greater regulatory leverage or lower purchasing power, not lower real costs of production. Furthermore, although trade usually benefits consumers, in the case of importation of pharmaceuticals the savings may accrue largely to intermediaries -- wholesalers or pharmacists -- not as lower prices to consumers, as discussed earlier. Although importation is sometimes justified as a stimulus to competition, such competition for on-patent products undermines the purpose of patents, which is protect originator firms from competition from perfect substitutes for the life of the patent, in order to permit the originator firm to price above marginal cost and hence recoup the fixed costs of R&D.

Given the cost structure of the research-based pharmaceutical industry, importation is likely to actually reduce economic efficiency, due to the high cost of R&D, which is a global joint cost, interacting with national systems of price regulation that exploit government's monopsony (large buyer) power. Global joint costs are costs that jointly benefit many consumers worldwide; these costs are independent of how many or which countries are served and hence cannot be attributed to specific countries. Pharmaceutical R&D is largely a global joint cost. It accounts for roughly 30 percent of the total cost of

bringing new drugs to market, if all costs are calculated in discounted present value (Danzon, 1997a).

Although joint costs, by definition, are not attributable to any specific set of consumers, somehow consumers overall must pay these costs if R&D is to continue. Economists have addressed the question of how to set prices to different users in order to cover joint costs, while yielding the highest social welfare. The resulting theory -- so-called Ramsey pricing -- implies that charging different prices is appropriate when consumer groups differ in their true price sensitivity (Ramsey, 1927; Baumol and Bradford, 1970; Danzon, 1997b). Price differentials lead to more efficient use of the product and a more efficient level of R&D than would a policy that results in uniform prices to all consumers.

Price differences do not imply cost shifting, contrary to widely held beliefs. On the contrary, the prices required in high-price countries to support a given level of R&D are lower if low-price countries remain in the market, paying prices that are sufficient to cover their country-specific marginal cost and make some contribution to joint costs, rather than being priced out of the market by a uniform higher price. For industries with this cost structure, including airlines and computer software, marginal cost pricing is not viable because it does not cover the fixed costs of product development.

The problem of recouping joint fixed costs of R&D is not unique to pharmaceuticals and is addressed through our system of patents. Patent protection is intended to enable innovators to charge prices above the marginal cost of production, in order to cover their R&D investment. Patent protection traditionally bars the sale of copy products during the life of the patent, including importation of the same product from abroad. The value of patent protection for pharmaceuticals is already significantly constrained in many countries by price regulation. Permitting importation of on-patent products magnifies this effect, by letting the low prices in one country spill over to other countries.

In countries with national insurance programs where the government is a monopsony (sole) purchaser of medicines, each government faces a strong temptation to force prices down to the marginal cost of supplying that country, free riding on others to pay for the joint costs of R&D. This strategy is attractive to buyers because the joint costs are sunk by the time prices are negotiated, and companies are willing to supply existing products as long as prices cover the short run marginal cost of production and distribution. However, if each country pays only its country-specific marginal cost -- either through direct regulation or by importing low prices from other, lower-price countries – then no one pays for the global joint costs of R&D. In the long run consumers will be worse off because they will not have access to some of the innovative pharmaceuticals that they would have been willing to pay for. At the limit, if prices are suppressed to the level of country-specific short run marginal cost in all countries, the revenue shortfall could be at least 50-70 percent of the total cost of bringing new pharmaceuticals to market.

As trade and/or regulation based on foreign prices lead to the break down of separate markets for drugs and a downward pressure on prices, economic theory predicts that manufacturers will adjust their pricing strategies by attempting to charge a single price in

all connected markets, in order to eliminate the price arbitrage opportunity. Several multinational companies already attempt to set launch prices within narrow bands in all countries of the EU, despite significant differences in income levels and health care systems. If the U.S. were linked to foreign markets by importation or by regulation based on foreign prices, other countries would inevitably see prices rise or drugs not launched at all. This clearly hurts patients in those nations but would also harm patients here. For each sale today, even at a price below a U.S. market price, revenues exceed marginal production costs. Were these sales not made, overall revenues from these countries would decline. Thus in the long run U.S. consumers will also lose. Importation and the resulting pressure for a uniform price policy will lead to lower global revenues and hence some innovative medicines will not be developed that consumers would have been willing to pay for.

Regulation vs. Competition

Just as some price differences exist today between the U.S. and other nations, differences also exist within the U.S. This is good news, not bad. The fact that today large managed care customers are able to negotiate price discounts confirms that competition can effectively work to restrain prices if given the chance. Such competition should be encouraged. The U.S. competitive model, which results in relatively high prices for some innovative, on-patent products but aggressive generic entry and price competition once patents have expired, yields much stronger incentives for innovation than regulatory systems that constrain prices for innovative drugs and also undermine competition from generics. If we want affordable drugs and the level and type of R&D that consumers and taxpayers, on average, are willing to pay for, then the best approach is to encourage competition between health plans, permit market-determined prices and permit international price differentials. Drug importation, which tries to import foreign price regulation, undermines appropriate price differentials. It will likely result in some higher prices abroad and significantly reduced access, with little if any benefit to US consumers.

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